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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,464

03/03/2006

Yves Mayeresse

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12/04/2008

GLAXOSMITHKLINE

CORPORATE INTELLECTUAL PROPERTY, MAI B482

FIVE MOORE DR., PO BOX 13398

RESEARCH TRIANGLE PARK, NC 27709-3398

EXAMINER

BLUMEL, BENJAMIN P

ART UNIT

PAPER NUMBER

1648

NOTIFICATION DATE

DELIVERY MODE

12/04/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/533,464	<b>Applicant(s)</b> MAYERESSE ET AL.	
	<b>Examiner</b> BENJAMIN P. BLUMEL	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-5 and 11-32 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 and 25-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5, 11-15, 20-22 and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

This application contains claims 16-19 and 25-32 are drawn to an invention nonelected without traverse in the reply filed on July 2, 2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicants are informed that the rejections of the previous Office action not stated below have been withdrawn from consideration in view of the Applicant's arguments and/or amendments.

Claims 2-5, 11-15, 20-22 and 24 are examined on the merits.

### ***Response to Arguments***

Applicant's arguments filed August 22, 2008 have been fully considered but they are not persuasive. See responses below.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either

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is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**(Prior Rejection Maintained)** Claims 2, 3, 12-15 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23, 27, 28, 30-35 and 40 of copending Application No. 10/533,462. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of the co-pending application and that of the instant application are obvious variants since each are drawn to compositions containing inactivated polio virus and polysaccharides or oligosaccharides and a stabilizing agent formulated as a dried composition. These compositions are contained in a liquid repellant container.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**(Prior Rejection Maintained)** Claims 2, 3 and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26, 34 and 36-41 of copending Application No. 11/587,023. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inventions of the co-pending application and that of the instant application are obvious variants since each are drawn to compositions containing inactivated polio virus and polysaccharides or oligosaccharides of bacteria and a stabilizing agent formulated as a dried highly viscous liquid. These compositions are contained in a liquid repellant container.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Response to Arguments:**

Applicants have argued that co-pending application '462 has the same PCT priority date as the instant application. Therefore, if the instant invention was patented, it would not create an "unjustified or improper timewise extension of the right to exclude granted by a patent." M.P.E.P. 804.

In response, '462 is a national stage entry of PCT/EP03/12191, where as the instant application is a national stage entry of PCT/EP03/12160, which are different PCT international applications. More importantly, 35 U.S.C. 101 "Inventions Patentable" recites: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain **a patent** therefor, subject to the conditions and requirements of this title." MPEP § 804 also states that: "The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that: 'The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.'"

Therefore, inventive entities are allowed to a patent to an invention and obvious variants (to one skilled in the art).

Applicants have also argued that co-pending application '023 has a PCT priority date of April 25, 2005, almost 1 1/2 years after the PCT priority date of this case. Applicants respectfully submit that issuance of their earlier filed application will not create an "unjustified or improper timewise extension of the right to exclude granted by a patent." M.P.E.P. 804.

In response, MPEP § 804 (I)(B) states that “provisional double patenting rejections should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications”. Therefore, since the 35 U.S.C. 103(a) rejection has been maintained, this provisional double patenting rejection is maintained. MPEP § 804 also states that: “The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The public policy behind this doctrine is that: ‘The public should . . . be able to act on the assumption that upon the expiration of the patent it will be free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made, taking into account the skill in the art and prior art other than the invention claimed in the issued patent.’”

Furthermore, whether the difference between the PCT priority is one day or 1.5 years doesn't allow any inventor to obtain two patents to similar/obvious inventions as discussed above.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**(Prior Rejection Maintained)** Claims 1-15, 20-22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boutriau et al. (WO 02/00249 A2), Kurikka et al. (Journal of Pediatrics, 1996), Troung-Le et al. (US 7,135,180 B2) and Volken et al. (US 6,051,238).

**Response to Arguments:**

Applicant's argue that Boutriau et al. shall not preclude patentability under 35 U.S.C. 103(a) as this application and Boutriau et al. were subject to an obligation of assignment to the same business entity at the time this invention was made. 35 U.S.C. 103(c)(1). M.P.E.P. 706.02(1)(2). The name of the private company SmithKline Beecham Biologicals S.A. (the assignee of Boutriau et al.) was changed to GlaxoSmithKline Biologicals S.A. (the assignee of this application). Therefore, Boutriau et al. and the present invention are commonly owned. Applicants have supplied copy of the Certificate of Name Change in their response.

In response, applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as Boutriau et al. at the time this invention was made, or was subject to a joint research agreement at the time this invention was made. However, reference Boutriau et al. additionally qualifies as prior art under subsection 35 U.S.C. 102(b), and therefore, is not

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disqualified as prior art under 35 U.S.C. 103(c). Boutriau et al. is considered a 35 U.S.C. 102(b) reference since it was published on January 3, 2002, whereas the foreign priority of the instant application is November 1, 2002.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN P. BLUMEL whose telephone number is (571)272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stacy B Chen/  
Primary Examiner, Art Unit 1648

/BENJAMIN P BLUMEL/  
Examiner  
Art Unit 1648